IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF GEORGIA
WAYCROSS DIVISION

WILLIAM GRIFFIN, Widower, and as Personal Representative of the Estate of SHIRLEY GRIFFIN, Deceased,	)	
Plaintiff,	)	
vs.	)	
	)	Case No. 5:06-CV-00075-BAE-JEG
PFIZER, INC., a foreign corporation, *Defendant.*	)	

DEFENDANT'S ANSWER AND DEFENSES

TO THE HONORABLE JUDGE OF SAID COURT:

NOW COMES Defendant Pfizer Inc. (improperly named in Plaintiff's Complaint as "Pfizer, Inc.") ("Pfizer" or "Defendant"), incorporating its Certificate of Interested Persons, filed contemporaneously herewith, and files this its Answer and Defenses to Plaintiff's Complaint ("Complaint"), and would respectfully show the Court as follows:

I.
PRELIMINARY STATEMENT

Plaintiff's Complaint violates Rule 8 of the Federal Rules of Civil Procedure and should be stricken in its entirety. Defendant objects to Plaintiff's Complaint to the extent it seeks to impose upon Defendant an obligation to respond to lengthy and overbroad allegations of fact in violation of Rule 8. Defendant will respond hereafter to the material allegations of Plaintiff's Complaint plead in conformity with Rule 8. All other such allegations are denied. Furthermore, all responses provided hereafter are made in a good faith attempt to respond to Plaintiff's improper Complaint within the time limits prescribed by law. As further information is

disclosed clarifying Plaintiff's claims and allegations pertinent to those claims, Defendant will provide, by way of amendment to this Answer as necessary or by response to proper discovery, information correcting or clarifying any responses made hereafter which are later learned to have been provided in error.

Plaintiff's Complaint does not state in sufficient detail when, if ever, Plaintiff's Decedent was prescribed or used Bextra®. Accordingly, this Answer can only be drafted generally. Defendant may seek leave to amend this Answer when discovery reveals the specific time periods in which Plaintiff's Decedent was prescribed and used Bextra®, if any.

This preliminary statement is incorporated by reference in its entirety in response to each and every Paragraph of Plaintiff's Complaint.

II.
ORIGINAL ANSWER

Response to Allegations Regarding Jurisdiction and Parties

1. In response to Paragraph 1 of Plaintiff's Complaint, Defendant admits that Plaintiff brought this civil action seeking monetary damages, but denies that Plaintiff is entitled to any relief or damages. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations concerning the amount in controversy, and, therefore, denies the same. However, Defendant admits that Plaintiff claims that the amount in controversy exceeds $75,000, exclusive of interests and costs. Defendant admits that, during certain periods of time, it marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all

times adequate and comported with applicable standards of care and law. Except as stated herein, Defendant denies any wrongful conduct, denies that Bextra® caused or contributed to Plaintiff's Decedent's death or Plaintiff's alleged injuries or damages, if any, and denies the remaining allegations in Paragraph 1 of Plaintiff's Complaint.

2. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 2 of Plaintiff's Complaint regarding whether Plaintiff is the Personal Representative of Plaintiff's Decedent's Estate and whether Plaintiff has standing to bring this action, and, therefore, denies the same. Except as stated herein, Defendant denies the allegations in Paragraph 2 of Plaintiff's Complaint.

3. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 3 of Plaintiff's Complaint regarding Plaintiff's and Plaintiff's Decedent's citizenship and marital status, and, therefore, denies the same. Except as stated herein, Defendant denies the allegations in Paragraph 3 of Plaintiff's Complaint.

4. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 4 of Plaintiff's Complaint regarding whether the listed persons are the survivors and beneficiaries of Plaintiff's Decedent, and, therefore, denies the same. Except as stated herein, Defendant denies the allegations in Paragraph 4 of Plaintiff's Complaint.

5. In response to Paragraph 5 of Plaintiff's Complaint, Pfizer admits that it is a Delaware corporation with its principal place of business in New York and that it does business in the State of Georgia. Defendant denies the remaining allegations in Paragraph 5 of Plaintiff's Complaint.

6. Defendant states that Paragraph 6 of Plaintiff's Complaint contains legal conclusions to which no response is required. To the extent that a response is deemed required, Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations concerning Plaintiff's citizenship and the amount in controversy, and, therefore, denies the same. However, Defendant admits that Plaintiff claims that the parties are diverse and that the amount in controversy exceeds $75,000, exclusive of interests and costs. Defendant denies the remaining allegations in Paragraph 6 of Plaintiff's Complaint.

7. Defendant states that Paragraph 7 of Plaintiff's Complaint contains legal conclusions to which no response is required. To the extent that a response is deemed required, Defendant admits that, during certain periods of time, Pfizer marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant denies any wrongful conduct, denies that it committed a tort in the State of Georgia, denies that it caused or contributed to Plaintiff's Decedent's death or Plaintiff's alleged injuries or damages, if any, and denies the remaining allegations in Paragraph 7 of Plaintiff's Complaint.

8. Defendant states that Paragraph 8 of Plaintiff's Complaint contains legal conclusions to which no response is required. To the extent that a response is deemed required, Defendant admits that it may be served with process through its registered agent, but denies that it committed a tort in the State of Georgia and denies the remaining allegations in Paragraph 8 of Plaintiff's Complaint.

9. In response to Paragraph 9 of Plaintiff's Complaint, Defendant admits that, during certain periods of time, it marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance

with their approval by the FDA. Defendant denies the remaining allegations in Paragraph 9 of Plaintiff's Complaint.

10. In response to Paragraph 10 of Plaintiff's Complaint, Defendant admits that, during certain periods of time, it marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA, and admits that it conducts business in the State of Georgia. By way of further responses, Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant further states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in Paragraph 10 of Plaintiff's Complaint.

11. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 11 of Plaintiff's Complaint regarding whether Plaintiff's Decedent was prescribed, provided and/or used Bextra® and, therefore, denies the same. Except as stated herein, Defendant denies the allegations in Paragraph 11 of Plaintiff's Complaint.

12. In response to Paragraph 12 of Plaintiff's Complaint, Defendant admits that, during certain periods of time, it marketed and co-promoted Bextra® throughout the United States, including Georgia, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant denies the remaining allegations in Paragraph 12 of Plaintiff's Complaint.

13. Defendant states that Paragraph 13 of Plaintiff's Complaint contains legal conclusions to which no response is required. To the extent that a response is deemed required,

Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 13 of Plaintiff's Complaint regarding the judicial district in which the asserted claim allegedly arose, and, therefore, denies the same. Defendant is further without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 13 of Plaintiff's Complaint regarding whether Plaintiff purchased and/or used Bextra® and, therefore, denies the same. Defendant admits that, during certain periods of time, it marketed and co-promoted Bextra® throughout the United States, including Georgia, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant denies any wrongful conduct, including committing a tort within the State of Georgia, and, therefore, denies the remaining allegations in Paragraph 13 of Plaintiff's Complaint.

Response to Factual Allegations

14. In response to Paragraph 14 of Plaintiff's Complaint, Defendant denies any wrongful conduct, and denies that Bextra® caused or contributed to Plaintiff's Decedent's death. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 14 of Plaintiff's Complaint regarding whether Plaintiff's Decedent used Bextra® and, therefore, denies the same. Except as stated herein, Defendant denies the remaining allegations in Paragraph 14 of Plaintiff's Complaint.

15. In response to Paragraph 15 of Plaintiff's Complaint, Defendant admits that Bextra® is in a class of drugs that are, at times, referred to as being non-steroidal anti-inflammatory drugs ("NSAIDs"). Defendant further admits, as indicated in its FDA-approved prescribing information, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary

dysmenorrhea. Defendant also admits that, during certain periods of time, it marketed and co-promoted Bextra® throughout the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant denies the remaining allegations in Paragraph 15 of Plaintiff's Complaint.

16. Defendant denies the allegations in Paragraph 16 of Plaintiff's Complaint. By way of further response, Defendant states that, during certain periods of time, it marketed and co-promoted Bextra® throughout the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA.

17. Defendant denies any wrongful conduct and, therefore, denies all allegations in Paragraph 17 of Plaintiff's Complaint. By way of further response, Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information.

18. In response to Paragraph 18 of Plaintiff's Complaint, Defendant denies any wrongful conduct, including concealing or minimizing the cardiovascular risks associated with Bextra®. By way of further response, Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant further states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Accordingly, Defendant denies all allegations in Paragraph 18 of Plaintiff's Complaint.

19. In response to Paragraph 19 of Plaintiff's Complaint, Defendant admits that, during certain periods of time, it marketed and co-promoted Bextra® throughout the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in

accordance with their approval by the FDA. Defendant denies the remaining allegations in Paragraph 19 of Plaintiff's Complaint.

20. Defendant denies any wrongful conduct, denies that Bextra® was or is defective, and, therefore, denies all allegations in Paragraph 20 of Plaintiff's Complaint. By way of further response, Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant further states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

21. In response to Paragraph 21 of Plaintiff's Complaint, Defendant denies that the warnings or prescribing information for Bextra® were inadequate. Rather, Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant further states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Accordingly, Defendant denies any wrongful conduct and, therefore, denies all allegations in Paragraph 21 of Plaintiff's Complaint.

22. In response to Paragraph 22 of Plaintiff's Complaint, Defendant states that the referenced April 7, 2005 FDA document speaks for itself and respectfully refer the Court to the FDA document for its actual language and text. Any attempt to characterize the document is denied. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 22 of Plaintiff's Complaint regarding Plaintiff's knowledge, and, therefore, denies the same. By way of further response, Defendant states that Bextra® was and

is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant further states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Except as stated herein, Defendant denies any wrongful conduct, denies that Bextra® caused or contributed to Plaintiff's Decedent's death, and denies the remaining allegations in Paragraph 22 of Plaintiff's Complaint.

23. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 23 of Plaintiff's Complaint regarding whether Plaintiff's Decedent used Bextra®, and, therefore, denies the same. Except as stated herein, Defendant denies the allegations in Paragraph 23 of Plaintiff's Complaint.

24. In response to Paragraph 24 of Plaintiff's Complaint, Defendant denies any wrongful conduct, denies that it failed to warn of the risks associated with the use of Bextra®, and denies that it had any obligation to warn the general consuming public, as alleged, including Plaintiff's Decedent. Rather, Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant further states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Accordingly, Defendant denies all allegations in Paragraph 24 of Plaintiff's Complaint.

Response to First Cause of Action

25. In response to Paragraph 25 of Plaintiff's Complaint, Defendant incorporates herein by reference its responses to each and every paragraph of Plaintiff's Complaint as if fully set forth herein.

26. In response to Paragraph 26 of Plaintiff's Complaint, Defendant denies any wrongful conduct, and denies that Bextra® was or is defective or unreasonably dangerous. Defendant further denies that its advertising or promotions for Bextra® were misleading, or that its warnings or instructions were or are inadequate. Rather, Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant further states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Accordingly, Defendant denies all allegations in Paragraph 26 of Plaintiff's Complaint, including all subparts.

27. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 27 of Plaintiff's Complaint regarding whether Plaintiff's Decedent used Bextra®, and, therefore, denies the same. Except as stated herein, Defendant denies the allegations in Paragraph 27 of Plaintiff's Complaint.

28. In response to Paragraph 28 of Plaintiff's Complaint, Defendant states that, in the ordinary case, Bextra® was expected to reach users and consumers without substantial change from the time of sale. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 28 regarding whether Plaintiff's Decedent used Bextra®, and, therefore, denies the same. By way of further response, Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant further states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Except as stated herein,

Defendant denies any wrongful conduct and denies the remaining allegations in Paragraph 28 of Plaintiff's Complaint.

29. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 29 of Plaintiff's Complaint regarding whether Plaintiff's Decedent used Bextra®, and, therefore, denies the same. Except as stated herein, Defendant denies the allegations in Paragraph 29 of Plaintiff's Complaint.

30. The allegations in Paragraph 30 of Plaintiff's Complaint are not directed towards Defendant, and, therefore, no response is required. To the extent a response is deemed required, Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies the remaining allegations in Paragraph 30 of Plaintiff's Complaint.

31. Defendant states that Paragraph 31 of Plaintiff's Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendant states that it met any and all duties imposed by law. By way of further response, Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant further states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies the remaining allegations in Paragraph 31 of Plaintiff's Complaint.

32. In response to Paragraph 32 of Plaintiff's Complaint, Defendant denies that the warnings and/or prescribing information for Bextra® were deficient, inadequate, unclear, misleading or ambiguous. Rather, Defendant states that the potential effects of Bextra® were

and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant further states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Accordingly, Defendant denies any wrongful conduct and, therefore, denies all allegations in Paragraph 32 of Plaintiff's Complaint.

33. Defendant denies any wrongful conduct, denies that Bextra® was or is defective and, therefore, denies all allegations in Paragraph 33 of Plaintiff's Complaint. By way of further response, Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant further states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

34. Defendant states that Paragraph 34 of Plaintiff's Complaint contains legal conclusions to which no response is required. To the extent that a response is deemed required, Defendant denies any wrongful conduct, denies that Bextra® was or is defective, denies that Bextra® caused or contributed to Plaintiff's Decedent's death or Plaintiff's alleged injuries or damages, if any, and, therefore, denies all allegations in Paragraph 34 of Plaintiff's Complaint.

35. Defendant denies any wrongful conduct, denies that Bextra® caused or contributed to Plaintiff's Decedent's death or Plaintiff's alleged injuries or damages, if any, denies that Plaintiff is entitled to any damages from Defendant, and, therefore, denies all allegations in Paragraph 35 of Plaintiff's Complaint.

36. Defendant denies any wrongful conduct, denies that Bextra® caused or contributed to Plaintiff's Decedent's death or Plaintiff's alleged injuries or damages, if any, and

denies the remaining allegations in the unnumbered paragraph following Paragraph 35 of Plaintiff's Complaint.

Response to Second Cause of Action

37. In response to Paragraph 36 of Plaintiff's Complaint, Defendant incorporates herein by reference its responses to each and every paragraph of Plaintiff's Complaint as if fully set forth herein.

38. Defendant states that Paragraph 37 of Plaintiff's Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendant states that it met any and all duties imposed by law. Defendant denies the remaining allegations in Paragraph 37 of Plaintiff's Complaint.

39. In response to Paragraph 38 of Plaintiff's Complaint, Defendant denies any wrongful conduct and denies that Bextra® caused unreasonably dangerous risks. Rather, Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant further states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Accordingly, Defendant denies all allegations in Paragraph 38 of Plaintiff's Complaint.

40. In response to Paragraph 39 of Plaintiff's Complaint, Defendant denies any wrongful conduct and, therefore, denies all allegations in Paragraph 39 of Plaintiff's Complaint, including all subparts. By way of further response, Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant further states that the potential effects of Bextra® were and are adequately described

in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

41. Defendant states that Paragraph 40 of Plaintiff's Complaint contains legal conclusions to which no response is required. To the extent that a response is deemed required, Defendant denies any wrongful conduct, denies that Bextra® was or is defective, denies that Bextra® caused or contributed to Plaintiff's Decedent's death or Plaintiff's alleged injuries or damages, if any, and, therefore, denies all allegations in Paragraph 40 of Plaintiff's Complaint.

42. Defendant denies any wrongful conduct, denies that Bextra® caused or contributed to Plaintiff's Decedent's death or Plaintiff's alleged injuries or damages, if any, denies that Plaintiff is entitled to any damages from Defendant, and, therefore, denies all allegations in Paragraph 41 of Plaintiff's Complaint.

43. Defendant denies any wrongful conduct, denies that Bextra® caused or contributed to Plaintiff's Decedent's death or Plaintiff's alleged injuries or damages, if any, denies that Plaintiff is entitled to any damages from Defendant, and, therefore, denies all allegations in the unnumbered paragraph following Paragraph 41 of Plaintiff's Complaint.

Response to Third Cause of Action

44. In response to Paragraph 42 of Plaintiff's Complaint, Defendant incorporates herein by reference its responses to each and every paragraph of Plaintiff's Complaint as if fully set forth herein.

45. Defendant denies any wrongful conduct, denies that Bextra® was or is unreasonably dangerous, and, therefore, denies all allegations in Paragraph 43 of Plaintiff's Complaint. By way of further response, Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant

further states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

46. In response to Paragraph 44 of Plaintiff's Complaint, Defendant admits that, during certain periods of time, it marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. By way of further response, Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant denies any wrongful conduct and denies the remaining allegations in Paragraph 44 of Plaintiff's Complaint.

47. Defendant denies any wrongful conduct, including making any negligent misrepresentations regarding Bextra®, and, therefore, denies all allegations in Paragraph 45 of Plaintiff's Complaint. By way of further response, Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant further states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

48. Defendant denies any wrongful conduct, including any making any misrepresentations regarding Bextra®, and, therefore, denies all allegations in Paragraph 46 of Plaintiff's Complaint. By way of further response, Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant further states that the potential effects of Bextra® were and are adequately described

in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

49. In response to Paragraph 47 of Plaintiff's Complaint, Defendant denies any wrongful conduct, denies that Bextra® was or is defective, and denies that it actively concealed adverse information regarding Bextra®. Defendant further denies any obligation to warn the general consuming public, as alleged, including Plaintiff's Decedent. By way of further response, Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant further states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Accordingly, denies all allegations in Paragraph 47 of Plaintiff's Complaint.

50. Defendant denies any wrongful conduct, including making any misrepresentations regarding Bextra®, and, therefore, denies all allegations in Paragraph 48 of Plaintiff's Complaint. By way of further response, Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant further states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

51. Defendant states that Paragraph 49 of Plaintiff's Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendant denies any wrongful conduct, including making any misrepresentations regarding Bextra®, and, therefore, denies all allegations in Paragraph 49 of Plaintiff's Complaint.

52. Defendant states that Paragraph 50 of Plaintiff's Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendant states that it met any and all duties imposed by law. By way of further response, Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Except as stated herein, Defendant denies the allegations in Paragraph 50 of Plaintiff's Complaint.

53. Defendant states that Paragraph 51 of Plaintiff's Complaint contains legal conclusions to which no response is required. To the extent that a response is deemed required, Defendant denies any wrongful conduct, including making any negligent misrepresentations regarding Bextra®, denies that Bextra® caused or contributed to Plaintiff's Decedent's death or Plaintiff's alleged injuries or damages, if any, and, therefore, denies all allegations in Paragraph 51 of Plaintiff's Complaint.

54. Defendant denies any wrongful conduct, denies that Bextra® caused or contributed to Plaintiff's Decedent's death or Plaintiff's alleged injuries or damages, if any, denies that Plaintiff is entitled to any damages from Defendant, and, therefore, denies all allegations in Paragraph 52 of Plaintiff's Complaint.

55. Defendant denies any wrongful conduct, denies that Bextra® caused or contributed to Plaintiff's Decedent's death or Plaintiff's alleged injuries or damages, if any, denies that Plaintiff is entitled to any damages from Defendant, and, therefore, denies all allegations in the unnumbered paragraph following Paragraph 52 of Plaintiff's Complaint.

Response to Fourth Cause of Action

56. In response to Paragraph 53 of Plaintiff's Complaint, Defendant incorporates herein by reference its responses to each and every paragraph of Plaintiff's Complaint as if fully set forth herein.

57. Defendant denies any wrongful conduct, including fraudulently or intentionally misrepresenting and/or concealing any material information regarding Bextra®, and, therefore, denies all allegations in Paragraph 54 of Plaintiff's Complaint. By way of further response, Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant further states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

58. Defendant denies any wrongful conduct, including fraudulently or intentionally misrepresenting any information regarding Bextra®, and, therefore, denies all allegations in Paragraph 55 of Plaintiff's Complaint.

59. Defendant denies any wrongful conduct, including making any false representations regarding Bextra®, and, therefore, denies all allegations in Paragraph 56 of Plaintiff's Complaint.

60. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 57 of Plaintiff's Complaint regarding whether Plaintiff's Decedent used Bextra® and, therefore, denies the same. By way of further response, Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Except as stated herein, Defendant denies any wrongful

conduct and, therefore, denies the remaining allegations in Paragraph 57 of Plaintiff's Complaint.

61. Defendant denies any wrongful conduct, including making any fraudulent or intentional misrepresentations, denies concealing any information, and, therefore, denies all allegations in Paragraph 58 of Plaintiff's Complaint. By way of further response, Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant further states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information.

62. In response to Paragraph 59 of Plaintiff's Complaint, Defendant denies any wrongful conduct, including making any fraudulent or intentional misrepresentations, and/or actively or fraudulently concealing any information, regarding Bextra®. Defendant further denies any obligation to warn the general consuming public, as alleged, including Plaintiff's Decedent. By way of further response, Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant further states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Accordingly, Defendant denies all allegations in Paragraph 59 of Plaintiff's Complaint, including all subparts.

63. Defendant states that Paragraph 60 of Plaintiff's Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendant denies any wrongful conduct, including making any fraudulent or intentional

misrepresentations, and/or concealing any information, regarding Bextra®, and, therefore, denies all allegations in Paragraph 60 of Plaintiff's Complaint.

64. Defendant states that Paragraph 61 of Plaintiff's Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendant states that it met any and all duties imposed by law. Defendant denies that it had any obligation to warn the general consuming public, as alleged, including Plaintiff's Decedent. By way of further response, Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Except as stated herein, Defendant denies the allegations in Paragraph 61 of Plaintiff's Complaint.

65. Defendant denies any wrongful conduct, including making any fraudulent or intentional misrepresentations regarding the safety and/or efficacy of Bextra®, and, therefore, denies all allegations in Paragraph 62 of Plaintiff's Complaint. Rather, Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant further states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information.

66. Defendant denies any wrongful conduct, including making any fraudulent or intentional misrepresentations, and/or concealing any information, regarding the safety and/or efficacy of Bextra®, and, therefore, denies all allegations in Paragraph 63 of Plaintiff's Complaint. Rather, Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant further states that

Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information.

67. Defendant states that Paragraph 64 of Plaintiff's Complaint contains legal conclusions to which no response is required. To the extent that a response is deemed required, Defendant denies any wrongful conduct, including making any fraudulent or intentional misrepresentations regarding Bextra®, denies that Bextra® caused or contributed to Plaintiff's Decedent's death or Plaintiff's alleged injuries or damages, if any, and, therefore, denies all allegations in Paragraph 64 of Plaintiff's Complaint.

68. Defendant denies any wrongful conduct, denies that Bextra® caused or contributed to Plaintiff's Decedent's death or Plaintiff's alleged injuries or damages, if any, denies that Plaintiff is entitled to any damages from Defendant, and, therefore, denies all allegations in Paragraph 65 of Plaintiff's Complaint.

69. Defendant denies any wrongful conduct, denies that Bextra® caused or contributed to Plaintiff's Decedent's death or Plaintiff's alleged injuries or damages, if any, denies that Plaintiff is entitled to any damages from Defendant, and, therefore, denies all allegations in the unnumbered paragraph following Paragraph 65 of Plaintiff's Complaint.

Response to Fifth Cause of Action

70. In response to Paragraph 66 of Plaintiff's Complaint, Defendant incorporates herein by reference its responses to each and every paragraph of Plaintiff's Complaint as if fully set forth herein.

71. Defendant states that Paragraph 67 of Plaintiff's Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendant denies the allegations in Paragraph 67 of Plaintiff's Complaint.

72. Defendant denies any wrongful conduct and, therefore, denies all allegations in Paragraph 68 of Plaintiff's Complaint.

73. Defendant states that Paragraph 69 of Plaintiff's Complaint contains legal conclusions to which no response is required. To the extent that a response is deemed required, Defendant denies any wrongful conduct and, therefore, denies all allegations in Paragraph 69 of Plaintiff's Complaint.

74. Defendant states that Paragraph 70 of Plaintiff's Complaint contains legal conclusions to which no response is required. To the extent that a response is deemed required, Defendant denies any wrongful conduct, denies that Bextra® caused or contributed to Plaintiff's Decedent's death or Plaintiff's alleged injuries or damages, if any, and, therefore, denies all allegations in Paragraph 70 of Plaintiff's Complaint.

75. Defendant states that Paragraph 71 of Plaintiff's Complaint contains legal conclusions to which no response is required. To the extent that a response is deemed required, Defendant denies any wrongful conduct, denies that Bextra® caused or contributed to Plaintiff's Decedent's death or Plaintiff's alleged injuries or damages, if any, denies that Plaintiff is entitled to any damages from Defendant, and, therefore, denies all allegations in Paragraph 71 of Plaintiff's Complaint.

76. Defendant denies any wrongful conduct, denies that Bextra® caused or contributed to Plaintiff's Decedent's death or Plaintiff's alleged injuries or damages, if any, denies that Plaintiff is entitled to any damages from Defendant, and, therefore, denies all allegations in the unnumbered paragraph following Paragraph 71 of Plaintiff's Complaint.

Response to Demand for Trial By Jury and Costs

Defendant denies any wrongful conduct, denies that Bextra® caused or contributed to Plaintiff's Decedent's death or Plaintiff's alleged injuries or damages, if any, denies that Plaintiff is entitled to any damages from Defendant, and, therefore, denies all allegations set forth in the unnumbered paragraph of Plaintiff's Complaint entitled "Demand for Trial by Jury and Costs". Defendant further denies each and every allegation or averment contained in Plaintiff's Complaint not otherwise specifically responded to in this Answer, including, but not limited to, each and every unnumbered allegation or averment, each and every "WHEREFORE" provision, and any and all allegations implied in any heading for any section of Plaintiff's Complaint.

III.
AFFIRMATIVE DEFENSES

Defendant reserves the right to rely upon any of the following or additional defenses and matters of avoidance to claims asserted by Plaintiff to the extent that such defenses are supported by information developed through discovery or evidence at trial. Defendant affirmatively shows that:

First Defense

1. Plaintiff's Complaint fails to state a claim upon which relief can be granted.

Second Defense

2. Bextra® is a prescription medical product. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical products. Defendant's labeling and warning of Bextra® was at all times in compliance with applicable federal law. Plaintiff's causes of action against Defendant, therefore, fail to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

Third Defense

3. At all relevant times, Defendant provided proper warnings, information and instructions for the drug in accordance with generally recognized and prevailing standards in existence at the time.

Fourth Defense

4. At all relevant times, Defendant's warnings and instructions with respect to the use of Bextra® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed and distributed.

Fifth Defense

5. Plaintiff's action is time-barred as it is filed outside of the time permitted by the applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendant.

Sixth Defense

6. Plaintiff's action is barred by the Statute of Repose.

Seventh Defense

7. If Plaintiff or Plaintiff's Decedent sustained any injuries or incurred any losses or damages as alleged in Plaintiff's Complaint, the same was caused by the negligence of Plaintiff or Plaintiff's Decedent, and/or those acting at their direction or control, in failing to exercise due and proper care under the existing circumstances and conditions, thereby barring recovery or reducing Plaintiff's damages by the doctrines of contributory or comparative negligence.

Eighth Defense

8. The proximate cause of the loss complained of by Plaintiff is not due to any acts or omissions on the part of Defendant. Rather, said loss is due to the acts or omissions on the part

of third parties unrelated to Defendant and for whose acts or omissions Defendant is not liable in any way.

Ninth Defense

9. If Plaintiff or Plaintiff's Decedent sustained any injuries or incurred any losses or damages as alleged in Plaintiff's Complaint, the same was caused by operation of nature or other supervening or intervening conduct of persons other than Defendant, and for whose conduct Defendant is not responsible, or with whom Defendant has no legal relation or legal duty to control.

Tenth Defense

10. If Plaintiff or Plaintiff's Decedent sustained any injuries or incurred any losses or damages as alleged in Plaintiff's Complaint, the same was caused by operation of nature, an idiosyncratic reaction, an act of God, or other supervening or intervening conduct of persons or entities other than Defendant, and for whose conduct Defendant is not responsible, or with whom Defendant has no legal relation to or legal duty to control.

Eleventh Defense

11. Defendant affirmatively denies that Defendant violated any duty owed to Plaintiff or Plaintiff's Decedent.

Twelfth Defense

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a "learned intermediary" in determining the use of the product. Bextra® is a prescription medical product, available only on

the order of a licensed physician. Bextra® provided an adequate warning to Plaintiff's Decedent's treating and prescribing physicians. Defendant therefore satisfied its duties under the "learned intermediary" doctrine, and Plaintiff's claims asserted in Plaintiff's Complaint are barred in whole or in part by the "learned intermediary" doctrine.

Thirteenth Defense

13. The claims asserted in Plaintiff's Complaint are barred, in whole or in part, because Bextra® was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.

Fourteenth Defense

14. Bextra® was at all times material to Plaintiff's Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Bextra® at the time of the occurrence of the injuries alleged by Plaintiff were legally adequate for its approved usages.

Fifteenth Defense

15. Plaintiff's causes of action are barred in whole or in part by the lack of a defect, as the Bextra® allegedly ingested by Plaintiff's Decedent was prepared in accordance with the applicable standard of care.

Sixteenth Defense

16. Plaintiff's and Plaintiff's Decedent's alleged injuries/damages, if any, were the result of unforeseeable alterations, improper handling, or other unforeseeable misuse or abnormal use of the product Bextra® by persons or entities other than Defendant or persons acting on its behalf after the product left the control of Defendant. Any liability of Defendant is therefore barred.

Seventeenth Defense

17. Plaintiff's and Plaintiff's Decedent's alleged damages were not caused by any failure to warn on the part of Defendant.

Eighteenth Defense

18. Plaintiff's claims are barred because Plaintiff's Decedent's injuries, if any, were the result of pre-existing and/or unrelated medical, genetic and/or environmental conditions unrelated to Bextra®; diseases or illnesses unrelated to Bextra®; subsequent medical conditions or natural courses of conditions of Plaintiff's Decedent unrelated to Bextra®; and/or idiosyncratic reactions of Plaintiff'.

Nineteenth Defense

19. Plaintiff and Plaintiff's Decedent knew or should have known of any risk associated with Bextra®; therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

Twentieth Defense

20. Plaintiff is barred from recovering against Defendant because Plaintiff's claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

Twenty-first Defense

21. Plaintiff's claims are barred in whole or in part under the applicable state law because the subject pharmaceutical product at issue was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

Twenty-second Defense

22. The manufacture, distribution and sale of the pharmaceutical product referred to in Plaintiff's Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiff's causes of action are preempted.

Twenty-third Defense

23. Plaintiff's claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

Twenty-fourth Defense

24. Plaintiff's claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

Twenty-fifth Defense

25. Plaintiff's claims are barred in whole or in part because Defendant provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

Twenty-sixth Defense

26. Plaintiff's claims are barred or limited to a product liability failure to warn claim because Bextra® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

Twenty-seventh Defense

27. Plaintiff's claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

Twenty-eighth Defense

28. Plaintiff's claims are barred under § 4, et seq. of the Restatement (Third) of Torts: Products Liability.

Twenty-ninth Defense

29. To the extent that Plaintiff is seeking punitive damages, Plaintiff has failed to plead facts sufficient under the law to justify an award of punitive damages.

Thirtieth Defense

30. The imposition of punitive damages in this case would violate Defendant's rights to procedural due process under the Fourteenth Amendment of the United States Constitution and the Constitution of the State of Georgia, and would additionally violate Defendant's right to substantive due process under the Fourteenth Amendment of the United States Constitution.

Thirty-first Defense

31. Under the facts in this action, punitive damages are inappropriate and Defendant moves to dismiss such claims. Any imposition of punitive damages against Defendant would violate its constitutional rights, including, but not limited to, its rights under the Fourth, Fifth, Sixth and Fourteenth Amendments of the United States Constitution, the ex post facto clause of Article 1, Section 10 of the United States Constitution and the parallel provisions of the Constitution of the State of Georgia or any other applicable state constitution. Imposition of punitive damages in this action would also violate Defendant's rights of equal protection. Defendant reserves the

right to assert any additional constitutional defenses to the imposition of punitive damages against it as may be disclosed during the course of additional investigation and discovery.

Thirty-second Defense

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

Thirty-third Defense

33. Plaintiff's punitive damage claims are preempted by federal law.

Thirty-fourth Defense

34. In the event that reliance was placed upon Defendant's nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendant.

Thirty-fifth Defense

35. Plaintiff and Plaintiff's Decedent failed to provide Defendant with timely notice of any alleged nonconformance to any express representation.

Thirty-sixth Defense

36. To the extent that Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Defendant's rights under the United States Constitution and the Constitution of Georgia.

Thirty-seventh Defense

37. Plaintiff's claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

Thirty-eighth Defense

38. Plaintiff's claim for punitive damages is barred by the proscription of the Eighth Amendment to the United States Constitution, as applied to the states through the Fourteenth Amendment, prohibiting the imposition of excessive fines, and by Art. 1 § 1, ¶ 17 of the Constitution of the State of Georgia. Furthermore, to the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused injuries asserted in Plaintiff's Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution and the Constitution of Georgia. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiff or Plaintiff's Decedent; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiff and Plaintiff's Decedent and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendant; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards;

(7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1, 111 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

Thirty-ninth Defense

39. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Bextra®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

Fortieth Defense

40. The claims asserted in Plaintiff's Complaint are barred because Bextra® was designed, tested, manufactured and labeled in accordance with the state-of-the-art industry standards existing at the time of the sale.

Forty-first Defense

41. If Plaintiff or Plaintiff's Decedent have sustained injuries or losses as alleged in Plaintiff's Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Defendant and over whom Defendant had no control and for whom Defendant may not be held accountable.

Forty-second Defense

42. The claims asserted in Plaintiff's Complaint are barred, in whole or in part, because Bextra® was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.

Forty-third Defense

43. Plaintiff's claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

Forty-fourth Defense

44. Plaintiff's claims are barred because Plaintiff's and Plaintiff's Decedent's injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiff, and were independent of or far removed from Defendant's conduct.

Forty-fifth Defense

45. The claims asserted in Plaintiff's Complaint are barred, in whole or in part, because Bextra® did not proximately cause injuries or damages to Plaintiff and Plaintiff's Decedent.

Forty-sixth Defense

46. The claims asserted in Plaintiff's Complaint are barred, in whole or in part, because Plaintiff and Plaintiff's Decedent did not incur any ascertainable loss as a result of Defendant's conduct.

Forty-seventh Defense

47. The claims asserted in Plaintiff's Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by

any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

Forty-eighth Defense

48. The claims must be dismissed because Plaintiff's Decedent would have taken Bextra® even if the product labeling contained the information that Plaintiff contends should have been provided.

Forty-ninth Defense

49. The claims asserted in Plaintiff's Complaint are barred because the utility of Bextra® outweighed its risks.

Fiftieth Defense

50. Plaintiff's damages, if any, are barred or limited by the payments received from collateral sources.

Fifty-first Defense

51. Defendant's liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiff's alleged damages, if any, are determined. Defendant seeks an adjudication of the percentage of fault of the claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiff and Plaintiff's Decedent.

Fifty-second Defense

52. Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

Fifty-third Defense

53. The claims asserted in Plaintiff's Complaint are barred, in whole or in part, because Bextra® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiff's claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Bextra®. Accordingly, Plaintiff's claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

Fifty-fourth Defense

54. Plaintiff's misrepresentation allegations are not stated with the degree of particularity required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

Fifty-fifth Defense

55. Defendant avails itself of all of the provisions, defenses, and standards of proof in O.C.G.A. § 51-12-5.1 concerning punitive damages.

Fifty-sixth Defense

56. Plaintiff's claims for strict liability are barred as to Defendant inasmuch as it is not a manufacturer of the drug Bextra® within the meaning of O.C.G.A. § 51-1-11(b)(1) and applicable Georgia law.

Fifty-seventh Defense

57. Plaintiff's claims for fraud and misrepresentation(s) are barred and should be dismissed because they have not been pled with sufficient particularity to meet the requirements of O.C.G.A. § 9-11-9(b).

Fifty-eighth Defense

58. Defendant reserves the right to supplement its assertion of defenses as it continues with its factual investigation of Plaintiff's claims.

Fifty-ninth Defense

59. Plaintiff's claims are barred, in whole or in part, by the doctrine of accord and satisfaction.

Sixtieth Defense

60. Plaintiff's damages, if any, are limited by the failure to mitigate by Plaintiff and/or Plaintiff's Decedent.

Sixty-first Defense

61. Plaintiff's damages, if any, are limited by the failure to mitigate by Plaintiff and/or Plaintiff's Decedent.

Sixty-second Defense

62. Defendant is entitled to credit for any settlement of claims for alleged injuries and damages made by Plaintiff with any other person or entity.

Sixty-third Defense

63. The claims asserted in Plaintiff's Complaint are barred, in whole or in part, by the doctrines of primary jurisdiction and exhaustion of administrative remedies, because the FDA has exclusive or primary jurisdiction over the matters asserted in Plaintiff's Complaint.

Sixty-fourth Defense

64. Defendant reserves the right to assert any additional affirmative defenses and matters of avoidance as may be disclosed during the course of additional investigation and discovery.

IV.
JURY DEMAND

Defendant hereby demands a trial by jury.

V.
PRAYER

WHEREFORE, Defendant having fully responded to Plaintiff's Complaint, demand:

a. **TRIAL BY JURY**;

b. That judgment be entered in its favor;

c. That any and all claims for compensatory damages, medical expenses, physical, mental and conscious pain and suffering or other personal injuries or damages or expenses be denied;

d. That any and all claims for special damages for medical expenses, lost wages, lost inheritance, lost earning capacity, physical pain and mental anguish, disfigurement and physical impairment, wrongful death and survival damages, loss of consortium, comfort, care and companionship be denied;

e. That any and all claims for punitive or exemplary damages be denied;

f. That all costs be taxed to Plaintiff; and

g. That this Court enter an award or such other and further relief to Defendant as it deems just and proper.

Respectfully submitted this 4th day of September 2007.

TROUTMAN SANDERS LLP

N. Karen Deming, Esq.
Georgia Bar No. 217581
Attorney for Defendant Pfizer Inc.

Bank of America Plaza, Suite 5200
600 Peachtree Street, N.E.
Atlanta, Georgia 30308-2216
(404) 885-3000 (telephone)
(404) 885-3900 (facsimile)

CERTIFICATE OF SERVICE

This is to certify that I have this day served the within and foregoing ***DEFENDANT'S ANSWER AND DEFENSES*** upon opposing counsel by United States Mail, postage prepaid and properly addressed as follows:

Roger J. Dodd, Esq.
Georgia Bar No. 224300
Attorney for Plaintiff
Spohrer, Wilner, Maxwell & Matthews, P.A.
701 W. Adams Street
Jacksonville, FL 32204

This 4th day of September 2007.

TROUTMAN SANDERS LLP

N. Karen Deming, Esq.
Georgia Bar No. 217581
Attorney for Defendant Pfizer Inc.